



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 4, 2016

David M. Wilson, Ph.D.
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation
Amendment – To update the terms of registration and revise expression levels in the
confidential statement of formula (CSF) and label.
Product Name: MON 87701
EPA Registration Number: 524-594
Application Date: March 7, 2016
OPP Decision Number: 514817

Dear Dr. Wilson:

The amended labeling and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable provided you comply with the revised terms of registration as set forth below:

- 1) The subject registration is limited to a combined yearly total of 15,000 acres for breeding purposes, agronomic testing, and producing seed in the United States and the Commonwealth of Puerto Rico.
- 2) Monsanto must submit reports on IRM monitoring and remedial action plans to the U.S. Environmental Protection Agency (EPA) annually by August 31st each year.
- 3) Upon the EPA's request, Monsanto must provide a report on the acreage where MON 87701 has been grown by State and territory.
- 4) Harvested seed are not allowed for sale as commercial seed in the U.S. under the terms of this registration, but any non-treated seed containing MON 87701 may be sold as grain.
- 5) MON 87701 soybean may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce soybean varieties with combined pesticidal traits.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 08/17/2016

Any CSFs other than those listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ann Sibold of my team by phone at (703) 305-6502 or via email at sibold.ann@epa.gov.

Sincerely,



Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant Label

MON 87701

Lepidopteran-Protected Soybean
(OECD Unique Identifier: MON-877Ø1-2)

Active Ingredients:

Bacillus thuringiensis Cry1Ac protein and the genetic material (vector PV-GMIR9) necessary for its production in MON 87701 (OECD Unique Identifier: MON-877Ø1-2) soybean ≤0.00091%*

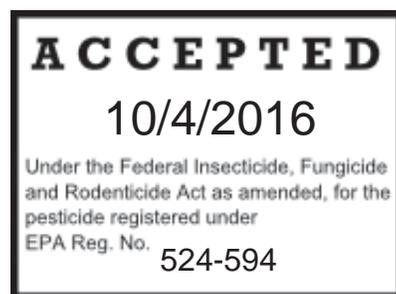
* Maximum percent (wt/wt) of dry grain.

Keep Out Of Reach Of Children

CAUTION

EPA Registration No. 524-594
EPA Establishment No. 524-MO-002

Monsanto Company
800 N. Lindbergh Blvd
St. Louis, MO 63167



NET CONTENTS _____ pounds of soybean seed

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

The following information must be included in the MON 87701 Grower Guide. This pesticide product may be used only for agronomic evaluation, seed increase and production in breeding nurseries as specified in the terms and conditions of this registration and on the labeling.

MON 87701 soybean may be combined through conventional breeding with other registered plant incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce soybean varieties with combined pesticidal traits.

Soybean has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k*) delta endotoxin protein for the control of the following lepidopteran soybean pests:

- | | |
|--------------------------------|-------------------------------|
| Soybean velvetbean caterpillar | <i>Anticarsia gemmatalis</i> |
| Soybean looper | <i>Pseudoplusia includens</i> |
| Soybean axil borer | <i>Epinotia aporema</i> |
| Sunflower looper | <i>Rachiplusia nu</i> |

The insect-protected soybean may be grown on up to 1,000 acres per county and up to a combined total of 15,000 acres per year in the United States (U.S.) and the territory of Puerto Rico.

Harvested seed are not allowed for sale as commercial seed in the U.S. under the conditions of this registration but any non-treated seed containing MON 87701 may be sold as grain.

Information regarding seed increase and production in breeding nurseries will be included in the Grower Guide.